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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/340,338	06/25/1999	SPIROS FOTINOS	1581/120	3768

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EXAMINER

WARE, TODD

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/05/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/340,338

Applicant(s)

FOTINOS, SPIROS

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-23,26-36 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-23,26-36 and 39-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt of request for extension of time (granted) and amendment both filed 8-5-02 is acknowledged. Claims 2, 6, and 24 have been canceled and claims 1, 7, 8, 10, 17, 21, 26 and 27 have been amended as requested. Claims newly filed as 37-39 have been re-numbered in accordance with 37 CFR 1.126 as 39-41, since claims 37-38 have been previously canceled (Paper # 8, filed 1-25-01). Claims 1, 3-5, 7-23, 26-36 and 39-41 are pending.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1, 3-5, 7-8, 13, 18-23, 27, 36, and 39-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Denzer (6,007,836; hereafter '836). Webster's (1988) is relied upon for providing the meaning of the term "rigid."

'836 discloses transdermal vasodilator systems for producing and maintaining the erection of a male penis comprising a combination of vasodilators such as prostaglandin E1, papaverine, phentolamine and polymer films (abstract; C7, L38-C8, L5; C8, L53-C9, L6). '836 also discloses the inclusion of isopropyl myristate and polyethylene glycol (C8, L41-52). The compositions of '836 produce an erection "on

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demand, immediately before sexual intercourse” and are therefore thought to be released in less than one hour. Furthermore, ‘836 discloses “anchoring the transdermal patch to the skin of the user” (C 8, L 3-4). It is the position of the examiner that this meets the instant requirement that the patch is rigid, since the specification does not appear to provide a clear indication of what is meant by the word “rigid” in the instant claims. Therefore, Webster’s New World Dictionary (1988), which defines rigid as “not moving; firmly fixed,” is relied upon to provide the meaning of the term.

Response to Arguments

3. Applicant’s arguments filed 8-5-02 have been fully considered but they are not persuasive.

Applicant argues that the instant claims are allowable over ‘836 on the basis that the instant claims require the disc to be “rigid.” This is not found persuasive. The instant specification does not appear to provide a clear indication of the meaning of the term. Accordingly, Webster’s New World Dictionary (1988) is relied upon to provide the meaning of the term. Page 1156 of Webster’s defines rigid as “not moving; firmly fixed.” ‘836 appears to meet this definition in column 8, lines 3-4 where it discloses “anchoring the transdermal patch to the skin of the user.” Accordingly, it is the position of the examiner that ‘836 meets the requirement that the patch is rigid. The instant claims have also been amended to recite “consisting essentially of” transitional language regarding the filmogenic polymer. For purposes of searching for and applying prior art, “consisting essentially of” is construed as equivalent to “comprising” and the burden is upon applicant to show that the introduction of additional steps or components would

materially change the characteristics of applicant's invention (MPEP 2111.03 and *In re Janakirama-Rao* 137 USPQ 893).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3-5, 7-8, 13, 17-23, 26-27, 29, 34-36, and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denzer (6,007,836; hereafter '836).

Webster's (1988) is relied upon for providing the meaning of the term "rigid."

'836 teaches transdermal vasodilator systems for producing and maintaining the erection of a male penis comprising a combination of vasodilators such as prostaglandin E1, papaverine, phentolamine and polymer films (abstract; C7, L38-C8, L5; C8, L53-C9, L6). '836 also discloses the inclusion of isopropyl myristate and polyethylene glycol (C8, L41-52). '836 does not teach the amount of polyethylene glycol to include in the composition. However, it is submitted that this is a manipulatable parameter that would be obvious to one skilled in the art at the time of the invention to manipulate in an effort to increase or decrease flexibility of the polymer film. The compositions of '836 produce an erection "on demand, immediately before sexual intercourse" and are therefore thought to be released in less than one hour. '836 does not state whether the penile surface requires pre-wetting. It is submitted that since it does not say that wetting the

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surface is required, no pre-wetting is necessary. It is also submitted that pre-wetting the surface would be obvious to one skilled in the art at the time of the invention to aid in adhesion of the patch to the skin, since this would aid in creating a vacuum. '836 also discloses "anchoring the transdermal patch to the skin of the user" (C 8, L 3-4). It is the position of the examiner that this meets the instant requirement that the patch is rigid, since the specification does not appear to provide a clear indication of what is meant by the word "rigid" in the instant claims. Therefore, Webster's New World Dictionary (1988), which defines rigid as "not moving; firmly fixed," is relied upon to provide the meaning of the term.

6. Claims 1, 3-5, 7-14, 17-23, 26-30, 34-36, and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denzer (6,007,836; hereafter '836) in view of Belsole (4,696,821; hereafter '821). Webster's (1988) is again relied upon for providing the meaning of the term "rigid."

'836 is relied upon for all that it teaches as stated previously. '836 does not teach the limitation where the filmogenic polymer is polyvinylpyrrolidone.

'821 is relied upon for teaching that polyvinylpyrrolidone film is an effective means for controlling the release of an active agent when administered transdermally. '821 also teaches the inclusion of plasticizers in the polyvinylpyrrolidone films wherein the plasticizer is PEG 400. The amount of plasticizer is unclear since '821 teaches weight per volume of liquid. Should applicants traverse on the grounds that the amount of plasticizer of '821 is outside the instant ranges, applicants are requested to submit

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evidence pertaining thereto. Furthermore, it is submitted that the ranges pertaining to the amount of plasticizer is a manipulatable parameter and it would be obvious to one skilled in the art at the time of the invention to adjust the amount of plasticizer in the composition to increase or decrease the flexibility of the film.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to construct the films of '836 from polyvinylpyrrolidone with the expectation that these films would control the release of drug from the patch and the motivation lying therein.

7. Claims 1, 3-5, 7-8, 13, 15-23, 26-27, 29, 31-36, and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denzer (6,007,836; hereafter '836) in view of Postaire (FR 2710649; hereafter '649). Webster's (1988) is again relied upon for providing the meaning of the term "rigid."

'836 is relied upon for all that it teaches as stated previously. '836 does not teach the limitation where the filmogenic polymer is a plant protein.

'649 is relied upon for teaching transdermal films formulated as a biodegradable patch comprising gliadin gel based on plant prolamines extracted from cereals (wheat) (abstract, p1).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to construct the polymer films of '836 from gliadin with the motivation to provide a transdermal patch to treat impotence that is biodegradable and the expectation that gliadin transdermal patches are biodegradable.

Response to Arguments

8. Since applicant's arguments are primarily directed toward overcoming the primary reference '836, the response to arguments under 35 USC 103(a) will be addressed concurrently. Applicant's arguments filed 8-5-02 have been fully considered but they are not persuasive.

Applicant argues that the instant claims are allowable over '836 on the basis that the instant claims require the disc to be "rigid." This is not found persuasive. The instant specification does not appear to provide a clear indication of the meaning of the term. Accordingly, Webster's New World Dictionary (1988) is relied upon to provide the meaning of the term. Page 1156 of Webster's defines rigid as "not moving; firmly fixed." '836 appears to meet this definition in column 8, lines 3-4 where it discloses "anchoring the transdermal patch to the skin of the user." Accordingly, it is the position of the examiner that '836 meets the requirement that the patch is rigid. The instant claims have also been amended to recite "consisting essentially of" transitional language regarding the filmogenic polymer. For purposes of searching for and applying prior art, "consisting essentially of" is construed as equivalent to "comprising" and the burden is upon applicant to show that the introduction of additional steps or components would materially change the characteristics of applicant's invention (MPEP 2111.03 and *In re Janakirama-Rao* 137 USPQ 893).

Conclusion

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9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 7:30 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

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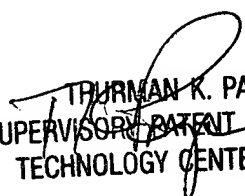
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw

October 31, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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